

Remarks

The Office Action mailed September 8, 2005, has been received and reviewed. Claims 25-30, 55-60 and 85-90 were elected in a response to a restriction requirement. Claim 91 was added. As such, claims 25-30, 55-60 and 85-90 and 91 are pending herein. Claims 25, 55, 85 and 91 have been amended. Applicants would like to thank the Examiner for taking the time to discuss this application on November 1, 2005. Reconsideration of the application in view of the following remarks is respectfully requested.

35 U.S.C. § 103(a) Rejections

Applicable Authority:

The basic requirements of a *prima facie* case of obviousness are summarized in MPEP §2143 through §2143.03. In order “[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success [in combining the references]. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).” MPEP § 2143. Further, in establishing a *prima facie* case of obviousness, the initial burden is placed on the Examiner. “To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in

light of the teachings of the references. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).” *Id.* See also MPEP §706.02(j) and §2142.

Obviousness Rejection Based on the Ichikawa, Evans and Reinhoff References

Claims 25-26, 29-30, 55-56, 59-60, 85-87 and 89-91 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Ichikawa reference (Internal Medicine (July 2000) Vol. 39, no. 7, pp. 523-524) in view of the Evans reference (Science (Oct. 1999) Vol. 286, pp 487-491) and the Reinhoff reference (US 2002/0049772 A1, filed 5/26/2000). Applicants submit that Ichikawa in view of Evans and Reinhoff fails to teach or suggest all the limitations of the rejected claims and traverse this rejection.

Independent claim 25, as amended herein, recites a method in a computer system for processing hereditary data related to the use of clinical agents by a person. The method comprises receiving a genetic test result value for the person and querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values. It is determined if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agent and an interpretation of the genetic test result value and the list of risk-associated agents is output.

Independent claim 55, as amended herein, recites computer system for processing hereditary data related to the use of clinical agents by a person. The system comprises a receiving component that receives a genetic test result value for the person and a querying component for querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values. The system further comprises a first determining component that determines if the genetic test result value is a polymorphism value associated with an atypical clinical event, an accessing component that accesses a list of risk-associated agents if the determining component determines that a genetic test result value is a

polymorphism value associated with an atypical event, and an outputting component that outputs an interpretation of the genetic test result value and the list of risk-associated agents.

Independent claim 85, as amended herein, recites a computer-readable medium containing instructions for processing hereditary data related to the use of clinical agents by a person. The instructions comprise receiving a genetic test result value for the person and querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values. The instructions further comprise determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agents and outputting an interpretation of the genetic test result value and the list of risk-associated agents.

Independent claim 91, as amended herein, recites a method in a computer system for processing hereditary data related to the use of clinical agents by a person. The method comprises receiving a genetic test result value for the person and querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values. The method further comprises determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agents. An interpretation of the genetic test result value and the list of risk-associated agents and it is determined if the person has been exposed to an agent on the list of risk-associated agents. It is submitted that no new matter has been added by way of the amendments to independent claims 25, 55, 85 and 91. *See* Page 9, Lines 1-3; Page 16, Line 8 - Page 17, Line 7; Page 16, Table 2; Page 21, Line 16 - Page 21, Line 2; and Original Claims 14, 44 and 74 of the Specification.

Applicants submit that the Ichikawa reference fails to teach or suggest querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, as recited in independent claim 25. The Ichikawa reference fails to teach or suggest, a computer system comprising a querying component for querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, as recited in independent claim 55. The Ichikawa reference fails to teach or suggest instructions on a computer readable medium that include a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, as recited in independent claim 85. The Ichikawa reference fails to teach or suggest querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, as recited in independent claim 91.

Rather, the method of the Ichikawa reference teaches that a particular single nucleotide polymorphism can be used to disclose severe side effects or proper dosage for a patient. The Ichikawa reference lacks any teaching or suggestion of querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values. The Ichikawa reference merely teaches a patient with an autosomal recessive trait for TMPT deficiency may show severe and potentially fatal leukopenia if treated with azathioprine or mercaptopurine. There is neither teaching nor suggestion in the Ichikawa reference to query a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values.

Like Ichikawa, the Evans reference also fails to teach or suggest a method in a computer system for a querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, as recited in independent claim 25. The

Evans reference also fails to teach or suggest, a computer system comprising a querying component for querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, as recited in independent claim 55. In addition, the Evans reference fails to teach or suggest instructions on a computer readable medium that include querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, as recited in independent claim 85. The Evans reference fails to teach or suggest querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, as recited in independent claim 91.

Rather, the Evans reference discloses translating functional genomics into rational therapeutics. The Evans reference provides examples of clinically relevant genetic polymorphisms influencing drug metabolism and effects. The Evans reference lacks any teaching or suggestion of querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values. The Evans reference merely chronicles the fact that automated systems are being developed to determine an individual's genotype for polymorphic genes. The discussion of automated systems is limited to automated systems for determining an individual's genotype and does not discuss querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values. There is no teaching or suggestion in Evans to query a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values.

Like Ichikawa and Evans, the Reinhoff reference also fails to teach or suggest a method in a computer system for a querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, as recited in independent

claim 25. The Reinhoff reference also fails to teach or suggest a computer system comprising a querying component for querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, as recited in independent claim 55. The Reinhoff reference fails to teach or suggest instructions on a computer readable medium that include querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, as recited in independent claim 85. The Reinhoff reference fails to teach or suggest querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, as recited in independent claim 91.

Rather, the Reinhoff reference teaches a computer program product for separating individuals into subpopulations using a polymorphic profile in a networked environment. Reinhoff says that when a polymorphism is known to be associated with a response to treatment, this information may be used to allocate the most appropriate dose to subjects enrolled in a treatment study such as a clinical trial. (Paragraph 0057) The polymorphic profiles of individuals can determine the degree of response of individuals to the treatment. Furthermore, as cited by the Examiner, the profile can be used as a diagnostic to identify patients appropriate for treatment when the decision to treat or a choice of treatment is made. There is no teaching or suggestion in Reinhoff to query a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values.

Applicants submit that Ichikawa in view of Evans and Reinhoff fails to teach or suggest all the limitations of the independent claims 25, 55, 85 and 91 and traverse this rejection. Further, as claims 26, 29-30, 56, 59-60, 86-87 and 89-90 depend directly or indirectly from

independent claims 25, 55 and 85, Applicants request withdrawal of the rejection of these claims as well.

Obviousness Rejection Based on the Ichikawa, Evans, Reinhoff and Fey
References

Claims 28, 58 and 88 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Ichikawa reference in view of the Evans reference and the Reinhoff reference and in further view of Fey et al. (US Pub. 20020038227, filed 2/26/01). Applicants submit that the Ichikawa reference in view of the Evans reference and Reinhoff reference and in further view of the Fey reference fail to teach or suggest all of the limitations of claims 28, 58 and 88.

As discussed above, the Ichikawa, Evans and Reinhoff references fail to teach or suggest all of the limitations of independent claims 25, 55 and 85. Dependent claims 28, 58 and 88 depend either directly or indirectly from independent claims 25, 55 and 85. The Fey reference also fails to teach or suggest all of the limitations of independent claims 25, 55 and 85.


Like Ichikawa, Evans and Reinhoff, the Fey reference also fails to teach or suggest a method for querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, as recited in independent claim 25. The Fey reference also fails to teach or suggest, a computer system comprising a querying component for querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, as recited in independent claim 55. Also, the Fey reference fails to teach or suggest instructions on a computer readable medium that include querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values, as recited in independent claim 85.

Rather, the Fey reference discloses a method for centralized health data management. The Fey reference relates to a centralized health screening and management system. Data and test results are transmitted to a centralized data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis. The Fey reference in no way suggests querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values. The Fey reference merely discusses storing health data in a manner that is accessible.

Applicants submit that the Ichikawa reference in view of the Evans reference and Reinhoff reference and in further view of the Fey reference fail to teach or suggest all of the limitations of claims 25, 55 and 85 from which claims 28, 58 and 88 depend either directly or indirectly. As such, Applicants request withdrawal of the 103(a) rejection of claims 28, 58 and 88.

In light of the above arguments, Applicants submit that claims 25-30, 55-60, and 85-91 are in condition for allowance. As such, Applicant respectfully request that a timely Notice of Allowance be issued in this case. Should there be any unresolved matters, please contact the undersigned.

Respectfully submitted,


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